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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,331	10/07/2003	Takashi Tokuyama	F-7995	5419

28107 7590 11/30/2006

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,331

Applicant(s)

TOKUYAMA ET AL.

Examiner

Randall Winston

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of receipt and entry of the amendment filed on 09/08/2006.

This action is made non-final due to a new ground of rejection.

Applicant's arguments have overcome examiner's 35 U.S.C. 102(e) and 103(a) rejection in his non-final office action of 03/03/2006.

The restriction requirement was made final in examiner's non-final office action of 03/03/2006. Thus, Group I, claims 23-47 and the election of species of a) ethanolamine b) 1,3-butyleneglycol c) antiphlogistic will be examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 and 43 rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a skin conditioner composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent, the specification does not enable any person skilled in the art to prepare a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state

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of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 6-56, examples 1-15, of the specification a skin conditioner composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent.

Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al. (US 5,753,214) in view of Madrange et al. (US 5143518) and Ikemoto et al. (US 6,497,898) as evidenced by Pearson et al. (6,951,658).

Applicant claims a skin conditioner composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent).

Yoshioka teaches (see, e.g. column 9 lines 1-35, column 17 lines 23-34) a composition comprising L-arginine (please note, as evidenced by Pearson et al. L-arginine is inherently found in rice, thus, it is considered a "rice preparation"), and an antiphlogistic agent (i.e. anti-inflammatory agent) used within a cosmetic composition to be applied to a subject's skin.

Yoshioka et al. do not expressly teach ethanolamine and a moisture retention agent of 1,3-butyleneglycol included within its cosmetic composition to be applied to a subject's skin.

Madrange et al. beneficially teaches (see, e.g. claim 15) ethanolamine contained within a cosmetic composition to be applied to a subject's skin.

Ikemoto et al. beneficially teaches (see, e.g. column 4 lines 44-53) 1,3-buteneglycol contained within a cosmetic composition to be applied to a subject's skin.

One of ordinary skill in the art of creating the claimed invention cosmetic skin conditioner composition would have been motivated to modify Yoshioka's cosmetic skin conditioner composition to include the other active ingredients as taught in Madrange and Ikemoto because the above combined three references would create an improved cosmetic skin conditioner composition to be applied to a subject's skin. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose..."

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition (i.e. the claimed treatment for atopic dermatitis and other claimed diseases of claims 43-47) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

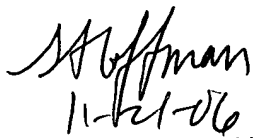
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Please note that the patentability of a product (i.e. L-arginine originated in a rice preparation and/or plant preparation) does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


11-21-06
SUSAN COE HOFFMAN
PRIMARY EXAMINER